§733.7

the Inspector General which will determine whether that office will elect to investigate the allegation.

§ 733.7 Referral to the contracting officer.

If the DOE Office of the Inspector General declines to investigate an allegation of research misconduct, the DOE Element should forward the allegation to the contracting officer responsible for administration of the contract or financial assistance agreement to which the allegation pertains.

§733.8 Contracting officer procedures.

Upon receipt of an allegation of research misconduct by referral under §733.7, the contracting officer should, by notification of the contractor or financial assistance recipient:

- (a) Require the contractor or the financial assistance recipient to act on the allegation consistent with the Research Misconduct requirements in the contract or financial assistance award to which the allegation pertains; or
- (b) In the event the contractor or the financial assistance recipient is unable to act:
- (1) Designate an appropriate DOE program to conduct an investigation to develop a complete factual record and an examination of such record leading to either a finding of research misconduct and an identification of appropriate remedies or a determination that no further action is warranted; and
- (2) Make the appropriate findings consistent with the Research Misconduct requirements contained in the contract or financial assistance award, in order to act in lieu of the contractor or financial assistance recipient.

PART 745—PROTECTION OF HUMAN SUBJECTS

Sec.

745.101 To what does this policy apply?

 $745.102 \quad Definitions.$

745.103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.

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745.107 IRB membership.

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745.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

745.111 Criteria for IRB approval of research.

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745.114 Cooperative research.

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745.116 General requirements for informed consent.

745.117 Documentation of informed consent.745.118 Applications and proposals lacking definite plans for involvement of human subjects.

745.119 Research undertaken without the intention of involving human subjects.

745.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.

745.121 [Reserved]

745.122 Use of Federal funds.

745.123 Early termination of research support: Evaluation of applications and proposals.

745.124 Conditions.

AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 7254; 42 U.S.C. 300y-1(b).

SOURCE: 56 FR 28012, 28018, June 18, 1991, unless otherwise noted.

§745.101 To what does this policy apply?

- (a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.
- (1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in §745.102(e), must comply with all sections of this policy.
- (2) Research that is neither conducted nor supported by a federal department or agency but is subject to